

Remarks

Declaration under 37 CFR 1.132

The inventor and Chief Executive Officer of the assignee, Nordic Naturals, Inc. hereby submits a declaration (Exhibit 1) evidencing commercial success of flavored fish oil capsules, as compared to other products, including: fish oil in unflavored capsules, flavored fish oil liquid, and unflavored fish oil liquid. Nordic Naturals' fish oil flavored capsules has an overall market penetration of 43% compared to all of the fish oil capsules sold in health stores in the United States. The superior market success is attributed substantially to the flavored capsules (see comparison between flavored and unflavored capsules in the declaration).

Claim Rejections – 35 USC § 112

Claim 1 has been amended to remove the reference to dissolving the flavoring in the other ingredients, however it is noted that the specification refers to melting the ingredients, and melting is synonymous with dissolving.

Claim Rejections – 35 USC § 103

Claims 1-9 were rejected under 35 USC 103(a) as unpatentable over Lachman in combination with US5,955,102 ('102). Claim 1 has been amended to require a concentration of water soluble flavoring greater than 0.2% which does not overlap Lachman (a single value of 0.1%). '102 does not mention flavoring. Claim 1, also requires a water concentration in the range of 6 to 10%. Lachman doesn't disclose the water content of dried capsules but starts at 50% water, and dries to an undisclosed value while keeping "the important plasticizer to gelatin ratio unchanged" indicating that water

was not recognized as an important variable. The Office Action states that “In any event the amount of water and plasticizer do not impart patentability to the claims, absent evidence to the contrary.” However, the declaration submitted in this case previously shows that the water content of the shell is a critical parameter in the flavored fish oil capsules because it determines the hardness of the shell and the permeability of shell to air. The more exposure of the fish oil to air, the greater is its deterioration.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). “All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). Claim 1 has claim limitations of greater than 0.2% flavoring and water in the range of 6% to 10%. These claim limitations are not found in the prior art alone or in combination.

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. “The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art.” *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). There is no suggestion or motivation in the prior art, individually

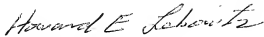
or in combination, to modify Lachman to $8\% \pm 2\%$ water or to use greater than 0.1% flavoring. Neither Lachman nor '102 teach or suggest anything at all about water content and Lachman is very specific to 0.1% flavoring.

Commercial Success – Since Lachman has been available to the public since 1976, perhaps the best evidence of non-obviousness of modifying Lachman is that there is no enabling reference in the prior enabling a flavored fish oil capsule, given the enormous commercial success of the applicant's invention.

Applicant believes that the application is now in condition for allowance and respectfully requests notice of allowance for claims 1 through 9.

Please contact the undersigned attorney for discussion of this application.

Respectfully submitted,

A handwritten signature in cursive script, reading "Howard E. Lebowitz".

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